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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/134,014	08/14/1998	WILHELM GRUISEM	018941-00020	7338

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[REDACTED] EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/134,014	Applicant(s)	Gruisrem et al
Examiner	FOX	Group Art Unit	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

7/22/02

Responsive to communication(s) filed on \_\_\_\_\_.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1 - 31 is/are pending in the application.

Of the above claim(s) 13 - 31 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1 - 12 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

Interview Summary, PTO-413

Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other \_\_\_\_\_

## Office Action Summary

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1638.

This application contains claims 13-31 drawn to an invention nonelected without traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants' amendments of 22 July 2002 and accompanying arguments have overcome the objection to the specification and the rejections of the claims under 35 USC 112, second paragraph and 35 USC 102.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8-12 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, with regard to non-exemplified types of recombination events, as stated on pages 3-4 of the last office action. The portion of the rejection regarding claims 4-6 and the use of a non-selectable reporter gene as part of the fusion protein construct has been withdrawn in view of Applicants' arguments of 22 July 2002.

Claims 1-4, 7-10 and 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Swoboda et al taken with Lyznik et al, as stated in the last office action.

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Claims 1-10 and 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Swoboda et al taken with Lyznik et al, further in view of Ow et al, as stated in the last office action.

Claims 1-4 and 7-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Swoboda et al taken with Lyznik et al, further in view of Miao et al, as stated in the last office action.

No claim is allowed.

Applicants' arguments filed 22 July 2002, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection is improper, given the assertions that the techniques described in the specification can be used to identify any type of recombination event, and given the failure of the Examiner to provide any evidence to support his position. The Examiner maintains that the specification itself demonstrates that particular types of recombination events were not in fact obtained (see, e.g., page 22, top paragraph). Furthermore, the Examiner has previously cited scientific publications to support his position that homologous recombination in plants is unpredictable. See also page 9 of Applicants' response of 22 July 2002, bottom paragraph, where the unpredictability inherent in the process is admitted by Applicants.

Applicants urge that the remaining art rejections are improper, given the failure of the prior art to teach recombination with an endogenous plant gene sequence, the failure of the prior art to suggest the combination of the two-plasmid system taught by Lyznik et al with the single

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plasmid system taught by Swoboda et al, the failure of the additional references to cure the deficiencies of the primary and secondary references, and the lack of a reasonable expectation of success.

The Examiner notes that the claims do not explicitly recite the use of an endogenous gene-encoding sequence, as part of the fusion protein-encoding sequence. Furthermore, the specification does not provide a definition of “endogenous”.

Regarding the motivation to combine, the Examiner maintains that both Swoboda et al and Lyznik et al teach the advantages of homologous recombination in plants, and that Lyznik et al teach the particular advantages of a promoterless construct for recombination with a strong endogenous gene promoter for optimal expression of the introduced gene, as stated in the last office action. Swoboda et al and Lyznik et al are further combinable because Lyznik et al is also drawn to a fusion construct comprising a GUS gene, i.e. a fusion between an intron and the GUS reporter gene. Thus, one of ordinary skill in the art would have been motivated to use the method of homologous recombination via fusion constructs taught by Swoboda et al and to modify that method by incorporating the promoterless homologous recombination constructs taught by Lyznik et al, given the recognition of the desirability of optimizing transgene expression.

Regarding the additional references, the Examiner maintains that the first two references were not deficient, as discussed above.

Regarding the alleged lack of reasonable expectation of success, the Examiner notes that Applicants' evidence of unexpected results, i.e. successful homologous recombination in plants,

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depends upon the use of a nucleic acid molecule comprising a fusion construct comprising at least one entire exon of the endogenous rbcL gene ligated to a non-selectable reporter gene, said nucleic acid molecule further comprising a selectable marker gene for the initial identification of transformed cells. In contrast, claims 1 and dependents are broadly drawn to any type of reporter gene including selectable or non-selectable reporters, any type of "polypeptide sequence of interest", and no mention of an additional selectable marker gene outside of the fusion protein-encoding construct. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 9, 2002

DAVID T. FOX  
PRIMARY EXAMINER

GROUP 100-1638

